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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/334,163	06/16/99	NAGEL	B MPS-411XC1

023557 HM22/1107  
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EXAMINER	
COLLINS, C	
ART UNIT	PAPER NUMBER
1638	12
DATE MAILED: 11/07/01	

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/334,163

Applicant(s)

NAGEL, BRUCE

Examiner

Cynthia Collins

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 August 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

Art Unit: 1638

### **STATUS OF THE APPLICATION**

1. The Amendment filed August 2, 2001, paper no. 11, has been entered.
2. Claims 1, 4, 5, 6, 10, 11 and 16 are newly amended.
3. Claims 12-15 and 17 have been cancelled.
4. Claims 1-11 and 16 are pending.
5. The following amendments to the specification are acknowledged: replacement of the paragraph found on page 9 lines 16-21.
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### **DETAILED ACTION**

#### ***Claim Rejections - 35 USC § 112***

7. Original Claims 2-3, 7-9 and 12 remain rejected, and newly amended claims 1, 4, 5, 6, 10, 11 and 16 are rejected, under 35 U.S.C. 112, first paragraph, for enablement, for the reasons of record set forth in the previous office action.
8. The Examiner acknowledges Applicant's statement that seeds of strains LS1498 and LS0417 have been deposited under the Budapest Treaty, and that those strains will irrevocably and without restriction or condition be released to the public upon issuance of a patent. The Examiner also Applicant's statement that a deposit is currently being arranged for seed of strain LS288, and that the specification and claims will be amended accordingly once Applicant receives a deposit receipt. Since the claims are currently directed to seed strain LS288, the claims are currently not enabled.
9. Newly amended claims 1, 6 and 16 are rejected, and original claims 2-3, 7-9 and 16 remain rejected, under 35 U.S.C. 112, first paragraph, for scope of enablement, for the reasons of record set forth in the previous office action.

Art Unit: 1638

10. Applicant argues that the rejection should be reconsidered in view of Applicant's amendments to the claims which have further specified the fatty acid profile of the claimed invention. Applicant further argues that it would be unreasonable to assert that the "Holeisyn" line is the only line capable of being manipulated through mutation breeding to yield subsequent lines having the claimed fatty acid profile. Additionally, Applicant argues that the amount of screening required to identify other lines having the claimed fatty acid profile would not constitute undue experimentation.

11. Applicant's arguments have been fully considered but are not found persuasive.

12. Applicant's amendments to the claims to further specified the fatty acid profile of the claimed invention does not overcome the rejection. Although amendments to the claims to further specify the fatty acid profile of the claimed invention narrows the scope of the claimed invention, corn seed with a mean saturate content of less than about 7.0%, a mean oleic acid content of at least 64.9%, and a mean linoleic acid content of 27.4% or less could still have different fatty acid profiles than those of 'LS1498', 'LS0417' and 'LS288' and still be encompassed by the breadth of the amended claims. The levels of other saturated fatty acids present in the corn seed oil are still not disclosed.

13. Furthermore, it is not asserted that the "Holeisyn" line is the only line capable of being manipulated through mutation breeding to yield subsequent lines having the claimed fatty acid profile. It is asserted that the specification does not provide evidence of the claimed fatty acid profile in the seed of mutants derived from corn plants other than the "Holeisyn" line. Additionally, the specification does not disclose the identification of the gene or genes that must be modified in or introduced into a corn plant to produce the claimed effect. Mutation breeding randomly introduces mutations into the genome. Mutation breeding cannot be specifically directed to alter a particular

Art Unit: 1638

gene or group of genes, and can result in the introduction of deleterious as well as desirable mutations. Consequently, mutation breeding is highly unpredictable. In the absence of evidence of the claimed fatty acid profile in the seed of mutants derived from corn plants other than the "Holeisyn" line, it would require undue experimentation to identify other appropriate parental lines. It is not the screening required to identify the claimed fatty acid profile in the seed of mutants derived from other corn plants that constitutes undue experimentation. It is the identification of appropriate parental lines that through mutation breeding would result in the claimed fatty acid profile that constitutes undue experimentation.

14. Given the lack of guidance in the specification regarding parental selection and the heritability of the various fatty acids influencing the total fatty acid content in corn seed oil, the absence of working examples directed to any other parent plants, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of genotype to fatty acid selection pressures, and the breadth of the claims which encompass any fatty acid profile with a mean saturate content of less than about 7.0%, a mean oleic acid content of at least 64.9%, and a mean linoleic acid content of 27.4% or less, undue experimentation would be required of the skilled artisan to make and or use the invention in its full scope.

15. The rejection of claims 5 and 11 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of cultivar names absent any deposit accession number, is withdrawn in view of Applicant's amendment of the claims to include the recitation of deposit accession numbers.

16. Newly amended claims 4 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of cultivar names absent any deposit accession number, in view of the failure of Applicant's amendment of the claims to include the recitation of deposit accession number for line LS288.

Art Unit: 1638

17. Original claims 2-3 remain rejected, and newly amended claims 1, 4 and 5 are rejected, under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "assemblage of corn seeds".

18. Applicant argues that it is very clear where the metes and bounds of the rejected claims lie, because the fatty acid profile has been specified and because anyone of skill in the art is able to determine whether a particular assemblage of seeds has a mean fatty acid profile fall within the explicit limitations of the claim.

19. Applicant's arguments have been fully considered but are not found persuasive.

20. Specification of the fatty acid profile does not clarify the metes and bounds of the rejected claims, notwithstanding the ability of one of skill in the art to determine a mean fatty acid profile. Given that the claims are not limited to seeds of the same cultivar, the recitation of "assemblage of corn seeds" could be interpreted as encompassing seeds that are genetically dissimilar that have only low amounts of saturated fatty acids in common which satisfy the claim limitations, making the claims indefinite.

21. The rejection of claim 12 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "commercially acceptable" is withdrawn in view of Applicant's cancellation of claim 12.

### SUMMARY

22. No claim is allowed.

23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the

Art Unit: 1638

mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached on (703) 308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and 1 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC  
November 4, 2001

A handwritten signature in black ink, appearing to read "Amy Nelson", with a stylized flourish at the end.

AMY J. NELSON, PH.D  
PRIMARY EXAMINER